DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 9, 2015

Davol Incorporated
Mr. Andrew Harrell
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K142808
Trade/Device Name: CapSure™ Permanent Fixation System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: February 3, 2015
Received: February 5, 2015

Dear Mr. Harrell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K142808

Device Name: CapSure™ Permanent Fixation System

The CapSure ™ Permanent Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____
Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

I. SUBMITTER

Davol Inc.
100 Crossings Boulevard
Warwick, RI 02886

Contact Person: Andrew Harrell
Regulatory Affairs Specialist
Phone: (401) 825-8472
Fax: (401) 825-8447
e-Mail: Andrew.Harrell@crbard.com

Date Prepared: March 7, 2015

II. DEVICE

Name of Device: CapSure™ Permanent Fixation System (product code GDW)
Common or Usual Name: Staple Implantable/Implantable Staple
Classification Name: Implantable staple (21 CFR §878.4750)
Regulatory Class: II
Product Code: GDW

III. PREDICATE DEVICE

K090470 ProTack™ Permanent Fastener System (Covidien Plc) - Cleared May 14, 2009
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The CapSure™ Permanent Fixation System is a sterile single use device that delivers either 15 or 30 permanent fasteners via a straight shaft. The shaft of the CAPSURE™ Permanent Fixation System is 37 cm in length. The fasteners are designed with a 316L Stainless steel helical coil and polyetheretherketone (PEEK) cap on the proximal end to support mesh or tissue.

V. INDICATIONS FOR USE

The CapSure™ Permanent Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

The Indications for Use statement for the subject device is essentially identical to the predicate device. Both the subject and predicate devices have the same intended use for the

approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device Comparison		
Device Features	**CapSure™ (Subject Device)**	**ProTack™ (K090470)**
Intended Use	Permanent soft tissue fixation	Permanent soft tissue fixation
Indication For use	Indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.	Fixation of prosthetic material and approximation of tissue in various surgical specialties, such as the repair of hernial defects.
Mesh/Tissue Retention Feature Material	Polyetheretherketone (PEEK) cap (injection molded)	Titanium (metal wire fabrication)
Fastener Material	316L Stainless Steel (metal wire fabrication)	Titanium (metal wire fabrication)
Fastener Body Contact	Same as predicate	Long term implant (>30 days) contacting tissue and/or bone
Fastener Shape/Design	Helical Coil/Screw with retention feature (proximal cap)	Helical Coil/Screw with retention feature (proximal tab)
Fastener Dimensions	4.2 mm overall fastener length 4.0 mm overall body diameter	4.0 mm overall fastener length 3.8 mm overall body diameter
Fastener Quantity per Device	15 & 30 fasteners	30 fasteners
Deployment component -Shaft Length	37 cm length	35.5 cm length
Deployment component Handle design	Same as predicate	Handle actuated-level delivery device
Fastener Delivery System	Same as predicate	Rotational – driven by inner shaft assembly
Device Sterilization	Same as predicate	EtO

VII. PERFORMANCE DATA

Performance Standards

No performance standards have been established for this device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the CapSure™ Permanent Fixation System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "*Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,*" May 1, 1995, and International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*," as recognized by FDA. The battery of testing included the following tests:

Device Testing

- Cytotoxicity
- Sensitization
- Irritation
- Pyrogen Testing

Implant Materials Testing

- Cytotoxicity
- Maximization Sensitization Study
- Intracutaneous Study
- Acute Systemic Toxicity Study
- Pyrogenicity
- Hemolysis
- Complement Activation Assay
- Intramuscular Implant – 12 Weeks
- Rabbit Femoral Bone Implant – 12 Weeks
- Rabbit Femoral Bone Implant – 26 Weeks
- Bacterial Reverse Mutation (Ames) Assay
- In Vitro Mouse Lymphoma Mutation Assay
- Mouse Peripheral Blood Micronucleus Test
- Subacute (14-Day) Intraperitoneal Toxicity Study Mice
- Subchronic (14-Day) Intravenous Toxicity Study Mice
- Subchronic (13-Week) Toxicity Study in Rats
- In Vivo Neurotoxicity
- Non-Volatile Residue
- Residue on Ignition
- Turbidity
- UV Absorption

The deployment device of the CapSure™ Permanent Fixation System is determined to be tissue contacting for duration of less than 24 hours, while the fasteners are determined to be permanent implants. The implantable fastener material conforms to ASTM F138 (316L Stainless Steel) and ASTM F2026 (PEEK).

All samples tested met the acceptance criteria.

Mechanical testing

The following non-clinical tests were completed for the subject and predicate devices. CapSure™ passed all the test requirements and showed substantial equivalence to the results of the predicate device - ProTack™.

- Trigger Force
- Mesh Compatibility
- Deployment Reliability
- MR Compatibility
- Burst Testing

All samples tested met the acceptance criteria.

Animal Studies
The following Animal *in vivo* studies were completed

- Porcine implantation strength study

CapSure™ passed all the test requirements and showed substantial equivalence to the results of the predicate device - ProTack™.

Clinical Studies
Clinical studies were not performed for this device nor were clinical studies performed for the predicate device, as they are not necessary to adequately assess the safety and effectiveness of the products.

VIII. CONCLUSIONS

The CapSure™ Permanent Fixation System is substantially equivalent to the legally marketed predicate device for the following reasons:

A) The same intended use and indications for use as the predicate device.
B) All devices use a similar fixation technology to deliver the fasteners by compressing an actuation lever.
C) Similar metallic coil fastener design that includes a feature to support mesh or tissue retention made of an inert, non-absorbable, biocompatible material.
D) Similar materials with long history of biocompatible use in medical instrumentation and implantation with appropriate testing data.
E) Similar technological characteristics to the predicate device such as: trigger handle, penetration depth, rotary delivery mechanism and shaft length.
F) Same principle of operation.

As demonstrated in the completed battery of bench and preclinical tests that were conducted by the company, minor technological differences between the CapSure™ Permanent Fixation System and the predicate device do not raise new questions of safety and effectiveness. The minor differences in technological characteristics have been tested and results demonstrate that the differences do not adversely affect the safety, effectiveness, or intended performance of the device. Testing included laboratory bench testing, biocompatibility testing, animal testing, and reliability testing, which result in the conclusion that the CapSure™ Permanent Fixation System is substantially equivalent to the legally marketed predicate device.